DEC 16 2011

zimmer spine

510(k) SUMMARY
Zimmer Spine Instinct™ Java® System

510(k) Number K113270

Date of Summary Preparation:	December 9, 2011
Submitter:	Zimmer Spine, Inc. 7375 Bush Lake Road Minneapolis, MN 55439
Company Contact:	Elsa A. Linke Regulatory Affairs
Manufacturer:	Zimmer Spine Cité Mondiale 23, parvis des Chartrons 33080 Bordeaux France
Device Name:	*Instinct Java* System
Common Name:	Spinal Fixation System
Classification Name:	Pedicle Screw Spinal System
Product Code:	MNI, MNH, NKB
Regulation Number:	888.3070
Device Classification:	Class III
Predicate Devices:	Zimmer Spine Instinct™ Java® System, K111301 Zimmer Spine Sequoia Spinal System, K082032

Description of Device:

The *Instinct Java* System is a temporary implant system used to correct spinal deformity in skeletally mature patients and facilitate the biological process of spinal fusion. This system is intended for non-cervical posterior use in the thoracic, lumbar and sacral areas of the spine. The *Instinct Java* spinal fixation system is indicated to achieve bony fusion via osteosynthesis at thoracic, lumbar and/or lumbosacral levels of the spine in documented cases of degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, spinal stenosis, kyphotic or lordotic spinal deformities, scoliosis, tumor and pseudoarthrosis or for revision of a failed previous fusion.

The system consists of implants and instruments. The implants consist of monoaxial and polyaxial pedicle screws of varying diameters and lengths, blockers, pre-contoured and straight rods, and transverse connectors of varying lengths. All implants are made of titanium alloy, with the exception of one commercially pure titanium component within the transverse connectors.

Re-usable surgical instruments are provided to facilitate placement of the implants.

In addition, the *Instinct Java* System is compatible with the transverse connectors currently cleared for the market as part of the Sequoia Spinal System, identified in K082032. Furthermore, the *Instinct Java* may be connected to the NexLink Band & In-Line Rod Connector, identified in K062505, K060634, K052566, K052247, K031985.

The implants and instruments are provided non-sterile. Instructions for Use are provided that contain validated cleaning and sterilization instructions for the user.

This system is intended to provide stabilization until a solid spinal fusion develops. The system may then be removed, per the surgeon's discretion. This decision should be made based on the risk/benefit ratio for each patient.

The subject of this 510(k) is the addition of screw and rod lengths, an alternative thread design on the pedicle screw head, a new driver, and new instrument containers and implant caddies.

Intended Use:

The *Instinct Java* spinal fixation system is designed for spinal fixation procedures in skeletally mature patients performed through a posterior approach. The *Instinct Java* spinal fixation system is indicated for the temporary realignment and stabilization of one or more intervertebral segments from the thoracic spine to the sacrum until bony fusion is obtained.

The *Instinct Java* spinal fixation system is indicated to achieve bony fusion via osteosynthesis at thoracic, lumbar and/or lumbosacral levels of the spine in documented cases of degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, spinal stenosis, kyphotic or lordotic spinal deformities, scoliosis, tumor and pseudoarthrosis, or for revision of a failed previous fusion.

Comparison of Technological Characteristics:

The *Instinct Java* Spinal System shares the same technological characteristics as the predicate devices. These characteristics include similar design, materials, range of sizes, technical requirements, and intended use. Determination of substantially equivalent performance characteristics in regard to the predicate devices was confirmed through dynamic compression bending and static torsion testing in conformance with the requirements of ASTM F-1717:2011a, and axial gripping capacity in conformance with the requirements of ASTM F-1798:97 (2008) and static tightening torque. In addition, cleaning and sterilization instructions were validated for the non-sterile components of the system.

Substantial Equivalence:

The *Instinct Java* Spinal System is substantially equivalent to the predicate devices in design, materials, function and intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

DEC 16 2011

Zimmer Spine, Inc.
% Ms. Elsa A. Linke
7375 Bush Lake Road
Minneapolis, Minnesota 55439

Re: K113270
Trade/Device Name: Instinct™ Java® System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH
Dated: November 11, 2011
Received: November 14, 2011

Dear Ms. Linke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K113270

Device Name: **Instinct™ Java® System**

Indications for Use:

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The *Instinct Java* spinal fixation system is indicated for the temporary realignment and stabilization of one or more intervertebral segments from the thoracic spine to the sacrum until bony fusion is obtained.

The *Instinct Java* spinal fixation system is indicated to achieve bony fusion via osteosynthesis at thoracic, lumbar and/or lumbosacral levels of the spine in documented cases of degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, spinal stenosis, kyphotic or lordotic spinal deformities, scoliosis, tumor and pseudoarthrosis, or for revision of a failed previous fusion.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical Orthopedic,
and Restorative Devices

510(k) Number K113270